IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION, Plaintiff, v. SMITH & NEPHEW, INC. Defendant.	C.A. No. 01-504-SLR
SMITH & NEPHEW, INC., Counterclaim Plaintiff, v. ARTHROCARE CORPORATION, AND ETHICON, INC., Counterclaim Defendants.	

SMITH & NEPHEW'S OPENING BRIEF IN SUPPORT OF ITS INEQUITABLE CONDUCT CASE

Dated: June 9, 2003

FISH & RICHARDSON P.C.
William J. Marsden, Jr. (#2247)
Keith A. Walter, Jr. (#4157)
919 N. Market Street, Suite 1100
P.O. Box 1114
Wilmington, DE 19899-1114
Telephone: (302) 652-5070

Mark J. Hebert
Thomas M. Johnston
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070

Kurtis D. MacFerrin
500 Arguello Street, Suite 500
Redwood City, California 94063
Telephone: (650) 839-5070

Attorneys for Defendant
SMITH & NEPHEW, INC.

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I. NATURE AND STAGE OF THE PROCEEDINGS

This is a patent infringement case in which the plaintiff ArthroCare Corp. ("ArthroCare") has accused the defendant Smith & Nephew, Inc. ("Smith & Nephew") of infringing three of ArthroCare's patents.

A. Procedural Background

There are six issues in this case which have been bifurcated into two phases. The issues of infringement, validity, and inequitable conduct were set for the first phase of the case, whereas the issues of damages, willfulness, and antitrust violation were bifurcated for the second phase of the case. An eight-day jury trial was held on the issues of validity and infringement from April 30, 2003 through May 9, 2003.

On May 12, 2003, the Court ruled that Smith & Nephew could submit its inequitable conduct case on the briefs (Tr. at 1701-02) (D.I. 418), with the schedule to be worked out between the parties (Tr. at 1749).[1] Smith & Nephew has tried to work out such a briefing schedule with ArthroCare, but has been unsuccessful. Although no briefing schedule has yet been agreed upon, this is Smith & Nephew's Opening Brief in Support of its Inequitable Conduct case, submitted in accordance with Smith & Nephew's proposed briefing schedule.

B. The Deposition of Examiner Mendez

In addition to submitting this opening brief, Smith & Nephew renews its request for leave to take the deposition of Examiner Mendez, and also seeks leave to supplement this brief with such deposition testimony, with respect to the '536 reexamination.

During the pretrial conference on April 15, 2003, Smith & Nephew raised the question of taking such a deposition and supplementing the inequitable conduct record, in

[1] Instead of discussing a briefing schedule for the inequitable conduct case with Smith & Nephew, on May 20, 2003 ArthroCare filed a Motion for Entry of Judgment of No Inequitable Conduct (D.I. 427, 428), in which it attempts to anticipate some of Smith & Nephew's inequitable conduct case. Smith & Nephew has opposed and moved to strike such motion as improper (D.I. 437).

the event that the Patent and Trademark Office ("PTO") granted permission to take the Examiner's deposition. (4/15/03 Hearing Tr. at 15-18) (D.I. 371). The Court indicated that it was willing to potentially consider such deposition testimony. (*Id.* at 35-36):

> So we're back to the examiner and I'd like to hear from Mr. Hebert whether it makes any sense to just kind of take up plaintiff's suggestion that this might be an issue that I would have a better feel for once I heard the evidence and that I guess we could supplement the record with deposition testimony if, after the conclusion of the evidence, I thought that, in fact, a deposition should be taken to clarify issues.

The Court also indicated that it would reserve a decision on the issue of the Examiner's deposition. (*Id.* at 36).

Following the completion of trial, the reexamination certificate for the '536 patent issued. Since the pendency of the reexamination was the only ground on which the PTO had denied Smith & Nephew's request to take the deposition of the examiner, and that ground was now moot, Smith & Nephew formally renewed its request with the PTO Solicitor's Office to take the deposition of Examiner Mendez. (Exhibit A to the accompanying Declaration of William J. Marsden In Support of Smith & Nephew's Opening Brief In Support Of Its Inequitable Conduct Case ("Marsden Dec.").[2] A favorable response is expected shortly.

Accordingly, Smith & Nephew should be given leave to take the deposition of Examiner Mendez, and supplement the inequitable conduct record with testimony from such deposition.

II. SUMMARY OF ARGUMENT

Proceedings in the PTO impose an "uncompromising duty" of candor and good faith on everyone involved in prosecution of the patent application. Violation of this duty

[2] In accordance with the Court's request, the accompanying Marsden Dec. also includes the trial exhibits, or -- in the case of the file histories -- the portions of the trial exhibits referred to herein.

is called "inequitable conduct" and results in the subject patent -- although it may still be valid -- being unenforceable due to equitable considerations.

Here, ArthroCare committed inequitable conduct in connection with each of the three patents in suit. The issues related to the '592 and '536 patents were previously pled. The issues related to ArthroCare's inequitable conduct in connection with the '882 patent, and particularly in connection with the Certificate of Correction obtained during prosecution of the '882 patent, are based on the testimony that came out at trial, particularly from Dr Goldberg and Mr. Raffle. In addition, under the unclean hands doctrine, because the three patents in suit are so closely related, the inequitable conduct in connection with any one or two of the patents taints the others, and renders them unenforceable as well.

ArthroCare committed inequitable conduct with respect to the '592 patent in overcoming the Examiner's rejection based on the prior art Roos '198 patent. In particular, ArthroCare's in-house patent attorney, Mr. John Raffle, deceived the PTO by misrepresenting the disclosure of the Roos '198 patent, by omitting material information about the teaching of the Roos '198 patent, particularly as found by Judge Orrick in the *ArthroCare v. Ethicon* case, and by making misleading arguments about other references. The Orrick opinion in particular was material information itself that was required to be submitted to the PTO pursuant to MPEP 2001.06(c). Yet Mr. Raffle did not do so.

With respect to the reexamination of the '536 patent, ArthroCare committed two types of inequitable conduct. The first relates to ArthroCare's failure to disclose Smith & Nephew's summary judgment briefs, the Taylor expert report, and the Roos Declaration, as required by MPEP 2001.06(c). The second is closely related to ArthroCare's inequitable conduct during prosecution of the '592 patent, and ArthroCare's arguments in overcoming the Roos '198 patent during such prosecution. In particular, Mr. Raffle had numerous off-the-record telephone conversations with the Examiner regarding the merits of the reexamination before a first Office Action on the merits and without filing timely

interview summaries, all in clear violation of the applicable Patent Office rules. It is believed that in these off-the-record communications, Mr. Raffle may have convinced the Examiner to simply parrot back the arguments that Mr. Raffle had previously made with respect to the Roos '198 patent during prosecution of the '592 patent without performing any independent analysis.

ArthroCare committed inequitable conduct with respect to the '882 patent in connection with obtaining the Certificate of Correction for claim 1 of the '882 patent. This is the Certificate of Correction that changed the scope of claim 1 of the '882 patent by broadening the claim to reduce the number of electrodes that were required by the claim from four to two. In obtaining the Certificate of Correction, Mr. Raffle made at least two affirmative misrepresentations, and also failed to explain how the so-called "correction" would broaden the claim when he clearly had a duty to do so.

III. STATEMENT OF FACTS

The relevant facts are set forth in the Argument sections, as appropriate.

IV. ARGUMENT

A. The Law Relating to Inequitable Conduct

The law relating to the issue of inequitable conduct derives from the fact that patent applications are prosecuted in secret *ex parte* proceedings which involve only the applicant and the patent examiner. Accordingly, the cases from the Supreme Court, the Court of Claims, the Court of Customs and Patent Appeals, and the Federal Circuit, have all consistently held that patent applicants and everyone involved in the application process have "an uncompromising duty of candor to the Patent Office."

1. Uncompromising Duty of Candor and Good Faith

Because proceedings in the Patent office are conducted on an *ex-parte* basis, the Supreme Court has explained that "[t]hose who have applications pending with the Patent Office ... have an uncompromising duty to report to it all facts concerning possible fraud

or inequitableness underlying the applications in issue." *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 818 (1945).

Thus, an applicant for a patent owes "the highest degree of candor and good faith" to the Patent Office. *Kingsland v. Dorsey*, 338 U.S. 318, 319 (1949); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1233 (Fed. Cir. 2003) ("It is well settled that patent applicants are required to prosecute patent applications 'with candor, good faith, and honesty.'") (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995)); *Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529, 1538 (Fed. Cir. 1984).

This duty of candor is predicated upon reasons of policy and practicality. By way of underlying purpose:

> [A] patent is an exception to the general rule against monopolies and to the right of access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.

Precision Instrument, 324 U.S. at 816; *The Proctor & Gamble Co. v. Kimberly-Clark Corp.*, 740 F.Supp. 1177, 1196 (D.S.C. 1989).

The Federal Circuit has observed that inequitable conduct can include "affirmative acts of commission, e.g., submission of false information, as well as omissions, e.g. failure to disclose material information." *J.P. Stevens & Co. v. Lex Tex Ltd., Inc.*, 747 F.2d 1553, 1559 (Fed. Cir. 1984).

The Federal Circuit articulated a two-step analysis -- involving findings of materiality and intent -- for determining whether inequitable conduct has been committed in *Halliburton Co. v. Schlumberger Technology Corp.*, 925 F.2d 1435, 1439-40 (Fed. Cir. 1991) (citations omitted) as follows:

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> The trial court must discern whether the withheld references satisfy a threshold level of materiality. The court must also determine whether

> the applicant's conduct satisfies a threshold showing of intent to mislead. . . . Next, assuming satisfaction of the thresholds, the trial court must balance materiality and intent. The more material the omission, the less culpable the intent required, and vice versa.

2. Materiality

Inequitable conduct requires both materiality and intent. *J.P. Stevens*, 747 F.2d at 1559-60. Inequitable conduct occurs by a patentee's "affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information." *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1233 (Fed. Cir. 2003)(quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995)). Information is material when "[i]t refutes, or is inconsistent with, a position the applicant takes in (i) Opposing an argument of unpatentability relied on by the [Patent] Office, or (ii) Asserting an argument of patentability." *37 C.F.R. § 1.56(b)(2)(i)-(ii).*

Prior to 1992, "Rule 56 defined information as 'material' when 'there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.'" *Molins PLC*, 48 F.3d at 1179, n.8. The Federal Circuit has "adopted this standard as the threshold standard of materiality." *Id.* While the PTO changed Rule 56, as reflected above, in 1992, the Federal Circuit has yet to comment on whether the change in the Rule will change its use of the "reasonable examiner" standard. *Id., see also Dayco Prods., Inc. v. Total Containment, Inc.*, 2003 WL 21203300, *5 (Fed. Cir. May 23, 2003) ("Thus, we have not decided whether the standard for materiality in inequitable conduct cases is governed by equitable principles or by the Patents Office's rules").[3] However, the Federal Circuit has applied the "reasonable examiner" standard to patents that were filed after the 1992 change to Rule 56. *See. e.g., Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed.

[3] Former commissioner Manbeck, who was involved in promulgating the new version of the rule, has testified that it was not intended to change the scope of Rule 56, but to simply make it more precise. *Boeringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F.Supp2d 508, 525-526 (D. N.J. 1999).

Cir. 2001). Whichever standard the Court eventually decides to employ, "intentional falsehoods and omissions [] would be plainly material under the newer PTO rule as well" as under the "reasonable examiner" standard. *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1322, n.2 (Fed. Cir. 2000).

The most highly material references are those that anticipate any of the patent's claims. *Fox Industries, Inc. v. Structural Preservation Systems, Inc.*, 922 F.2d 801, 804 (Fed. Cir. 1990). But a reference does not have to render a patent invalid to be material. *PerSeptive Biosystems, Inc.*, 225 F.3d at 1322; *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1421, (Fed. Cir. 1989); *Gardco Manufacturing, Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1214 (Fed. Cir. 1987); *A.B. Dick v. Burroughs Corp.*, 798 F.2d 1392, 1347 (Fed. Cir. 1986); *Consolidated Aluminum Corp. v. Foseco International Ltd.*, 910 F.2d 804, 812 (Fed. Cir. 1990); *RCA Corp. v. Data General Corp.* 701 F. Supp. 456, 474 (D. Del. 1988), *aff'd*, 887 F.2d 1056 (Fed. Cir. 1989); *Bristol-Myers Squibb*, 326 F.3d at 1237.

3. Intent to Mislead or Deceive

In *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) the Federal Circuit articulated the showing of intent required to support a finding of inequitable conduct as "intent to deceive."

Intent, while required, can usually only be inferred from circumstantial evidence. *Bristol-Myers Squibb*, 326 F.3d at 1239 ("Intent to mislead does not require direct evidence, and is typically inferred from the facts."); *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 882 F.2d 1556, 1562 (Fed. Cir. 1989); *Klein v. Peterson*, 866 F.2d 412, 415 (Fed. Cir. 1989); *Rohm & Haas Co. v. Crystal Chemical Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983).

Since adopting the "intent to deceive" standard in *Kingsdown*, the Federal Circuit and other courts have repeatedly emphasized that "[i]ntent need not, and rarely can, be proven by direct evidence." *Merck & Co.*, 873 F.2d at 1422; *see also Paragon Podiatry*

Laboratory, Inc. v. KLM Laboratories, Inc., 984 F.2d 1182, 1189-90 (Fed. Cir. 1993) ("'smoking gun' evidence is not required in order to establish an intent to deceive. ... Rather, this element of inequitable conduct, must generally be inferred from the facts and circumstances surrounding the applicant's overall conduct."); *LaBounty Mfg., Inc. v. U.S Intern. Trade Com'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992) ("Direct proof of wrongful intent is rarely available but may be inferred from clear and convincing evidence of the surrounding circumstances."); *Halliburton*, 925 F.2d at 1442; *Critikon Inc. v. Becton Dickinson Vascular Access Inc.*, 28 USPQ 2d 1362, 1370 n.2 (D. Del. 1993) ("Because direct evidence of an intent to deceive rarely exists, the Court may rely on circumstantial evidence leading to an inference of intent to mislead as the basis for a finding of inequitable conduct."); *Molins PLC v. Textron, Inc.*, 821 F. Supp. 1551, 1566 (D. Del. 1992); *Mushroom Associates v. Monterey Mushrooms Inc.*, 25 USPQ 2d 1304, 1310 (N.D. Calif. 1992) ("Rarely will there be direct evidence of a party's intent to deceive or mislead.... Such intent must frequently be determined from the facts and circumstances of the patent prosecution."); *Arcade Inc. v. Minnesota Mining & Manufacturing Co.*, 24 USPQ 2d 1578, 1588 (E.D. Tenn. 1991) ("The threshold level of intent does not require evidence of deliberate scheming and need not be shown by direct evidence."); *Carroll Touch Inc. v. Electro Mechanical Systems Inc.*, 24 USPQ 2d 1349, 1353 (C.D. Ill. 1992) ("Deliberate conduct can be inferred from the fact that the applicant had knowledge of the material information."), *aff'd in part & vacated in part*, 15 F.3d 1573 (Fed. Cir. 1993); *Black and Decker Inc. v. Hoover Service Center*, 765 F. Supp. 1129, 1137 (D. Conn. 1991).

Intent may be inferred from clear materiality -- sometimes reinforced by the patentee's complete absence of good faith justification for the failed conduct. *Nintendo of America Inc. v. Magnavox Inc.*, 10 USPQ 2d 1504, 1507 (S.D.N.Y. 1989) ("inferences of intent may be drawn from considerations touching on materiality and an applicant's knowledge thereof"); *Proctor & Gamble*, 12 USPQ 2d at 1593-94 (Stating that where

materiality is clear it is "difficult to establish 'subjective good faith' sufficient to prevent the drawing of an inference of intent to mislead.") (quoting *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415-16 (Fed. Cir. 1987); *see also Critikon, Inc.*, 120 F.3d at 1256 ("intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application."); *see also Brasseler*, 267 F.3d at 1375-76, 1380 (same). "Further, where withheld information is material and the patentee knew or should have know of that materiality, he or she can expect to have great difficulty in establishing subjective good faith sufficient to overcome an inference of intent to mislead." *Bristol-Myers Squibb*, 326 F.3d at 1239.

In *LaBounty*, the Federal Circuit pointed out:

> No single factor or combination of factors can be said always to require an inference of intent to mislead; yet a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish "subjective good faith" sufficient to prevent the drawing of an inference of intent to mislead. "A mere denial of intent to mislead (which would defeat every effort to establish inequitable conduct) will not suffice in such circumstances."

LaBounty, 958 F.2d at 1076 (quoting *FMC Corp.*, 835 F.2d at 1416). Similarly, in its most recent pronouncement on the law of inequitable conduct, the Federal Circuit explained that "the determination that Mr. Pilard knew of the significance of the [withheld information] in combination with the finding that he knew of the duty to disclose is sufficient to establish intent." *Bristol-Myers Squibb*, 326 F.3d at 1240.

The materiality and intent standards are balanced -- i.e. the more material a reference, the lesser the degree of intent that must be proved to establish inequitable conduct. *Bristol-Myers Squibb*, 326 F.3d at 1234 ("when balanced against high materiality, the showing of intent can be proportionally less"); *Halliburton*, 925 F.2d at

1439. Once inequitable conduct is found, all claims of the patent are unenforceable. *Bristol-Myers Squibb*, 326 F.3d at 1233; *J.P. Stevens*, 747 F.2d at 1561.

B. Specific Instances of Inequitable Conduct In Connection With ArthroCare's Patents

Smith & Nephew relies on inequitable conduct committed by ArthroCare and its representatives in connection with the procurement of the '592 and '882 patents and the reexamination of the '536 patent. The issues related to the '592 and '536 patents were previously pled. The issues related to ArthroCare's inequitable conduct in connection with the '882 patent, and particularly in connection with the Certificate of Correction obtained during prosecution of the '882 patent, are based on the testimony that came out at trial, particularly from Dr. Goldberg and Mr. Raffle.[4] In addition, under the unclean hands doctrine, because the three patents in suit are so closely related, the inequitable conduct in connection with any one or two of the patents taints the other patent(s) such that all three are unenforceable. *See Consolidated Aluminum v. Foseco International*, 910 F.2d 804, 810 (Fed. Cir. 1990).

1. ArthroCare's Inequitable Conduct In Connection With The '592 Patent

ArthroCare committed inequitable conduct with respect to the '592 patent in overcoming the Examiner's rejection based on the prior art Roos '198 patent. (U.S. Patent No. 4,116,198, DTX-11, Exhibit B). At the time, virtually all of the pending claims stood rejected over the Roos '198 patent. The rejection was based on the

[4] The court should liberally amend pleadings to conform to the evidence at trial. Fed. R. Civ. P. 15(a) ("[L]eave shall be freely given when justice so requires."); *see Fernandez v Haynie*, 31 Fed. App. 816 (4th Cir. 2002) (finding that the district court did not abuse its discretion in allowing party to amend his pleading to conform to the evidence); *Dealyne v. Commissioners of Lewes*, 416 F.2d 290, 298 (3d Cir. 1969) (citing *Newman v. Zinn*, 164 F.2d 558, 559-560 (3d Cir. 1947)) ("Under the Federal Rules of Civil Procedure ... the plaintiff is not bound by the theory of his pleadings. He may offer his proof and conform his pleadings to the proof offered 'when the presentation of the merits of the action will be subserved thereby.'"); *Rhone-Poulenc Agro S.A. v. Monsanto Co.*, 73 F.Supp.2d 537 (M.D.N.C. 1999) (patent infringement defendant was allowed to amend pleadings at close of discovery in order to assert claim that patent was obtained by inequitable conduct, and thus was unenforceable).

Examiner's understanding that the Roos '198 patent inherently disclosed the use of electrically conducting fluid, which was required by the claims of the '592 application.

In overcoming the Examiner's rejection, ArthroCare's in-house patent attorney, Mr. John Raffle, deceived the PTO by misrepresenting the disclosure of the Roos '198 patent, by omitting material information about the teaching of the Roos '198 patent, particularly as found by Judge Orrick in the earlier *ArthroCare v. Ethicon* case, and by making misleading arguments about other references -- without bothering to discuss the Elsasser and Roos article which undercut those arguments. Smith & Nephew's proof of such inequitable conduct is supported by the trial testimony of both Mr. Raffle and Smith & Nephew's expert Dr. Taylor (whose testimony was not rebutted at trial), as well as the file history for the '592 patent and the disclosures of the relevant prior art references.

a. The Rejection Based on the Roos '198 Patent

On February 29, 2000, the PTO issued an Office Action rejecting virtually all of the claims of ArthroCare's application for the '592 patent as either anticipated by the Roos '198 patent alone, or rendered obvious by the Roos '198 patent in combination with some other reference. (DTX-301 at 13-17, Exhibit C). In the Office Action, the Examiner characterized the Roos '198 patent as follows (*Id.* at 16) (emphasis added):

> The device includes a spaced return electrode as shown by Figure 1. A washing fluid passes through the axial lumen of the device. *Since the return electrode is removed from the body structure, a conductive fluid must complete the current flow path.*

The language used by the Examiner in the last sentence -- "a conductive fluid *must* complete the current flow path" -- meant that the Examiner understood the disclosure of conductive fluid in the Roos '198 patent to be "necessarily present," or in other words "inherent," rather than explicit. *See, e.g., Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

Accordingly, in preparing his Office Action it is clear that the Examiner did not actually review claim 1 of the Roos '198 patent.[5] Had he done so, the Examiner certainly would have referred to claim 1 of the Roos '198 patent as supporting his rejection. He certainly would not have issued a rejection based on *inherency* grounds, since claim 1 of the Roos '198 patent explicitly discloses electrically conductive fluid as follows (DTX-11 at col. 7, lines 59-62) (emphasis added):

> [A] space being formed between said treatment electrode and said neutral electrode which is adapted to be filled with *liquid to provide electrical conductance* between said electrodes.

b. The Disclosure of Electrically Conductive Fluid in Roos

It is clear that the "liquid to provide electrical conductance" in claim 1 of the Roos '198 patent is the same as "electrically conductive fluid" as used in the '592 patent, for at least two reasons:

First, the words used in claim 1 of the Roos '198 patent clearly meet this Court's interpretation of "electrically conductive fluid" (4/9/03 Memorandum Order at 3) (D.I. 383):

> "[E]lectrically conducting fluid" and "electrically conductive fluid" shall be construed to mean "any fluid that facilitates the passage of electrical current."

In its definition, all the Court required was that the fluid "facilitate[] the passage of electrical current." Of course, a "liquid" is a type of "fluid," and since "facilitate" means simply "to make easier," a "liquid to *provide* electrical conductance" in claim 1 of the Roos '198 patent squarely meets this Court's definition of "any fluid that *facilitates* the passage of electrical current."

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[5] *See, e.g.*, *Bristol-Myers Squibb*, 326 F.3d at 1236 ("The lack of any objective evidence that the Examiner reviewed the article in connection with his review of the '011 patent application supports the court's finding that the JACS article was not before the PTO in its review of the '011 patent application.").

Second, it was *undisputed* at trial that the Roos '198 patent disclosed the use of electrically conductive fluid. Here is the testimony of Dr. Taylor, Smith & Nephew's expert, on the issue (Tr. at 1301-03) (D.I. 416) (emphasis added):

> Q. Dr. Taylor, have you prepared a slide to tell the jury what the Roos '198 patent is about?
>
> A. Yes, I have. ...
>
> The Roos '198 patent basically follows up on the work that Doctors Elsasser and Roos did in their article and it's a bipolar electrosurgical device for the treatment of prostate and bladder tissue, commonly known as TURP.
>
> * * *
>
> Q. Have you done an element-by-element comparison of the teachings of the Roos '198 with the claims of the '536 patent?
>
> A. Yes, I have.
>
> Q. Have you prepared some slides to illustrate that?
>
> A. Yes, I have. ...
>
> *It also requires an electrically conducting fluid supply, directed to the target site and generating current, flow path between the active and return electrode. That is diagramatically shown here in Figures 7 and 8 and also specifically called out in Claim 1, basically the last line in Claim 1. So that element is satisfied.*
>
> Q. *Just to pause on this one for a moment, that language that is quoted below the drawing comes from Claim 1 of the Roos '198 patent?*
>
> A. *That's correct.*
>
> Q. *That is where you found support for the electrically conduct[ing] fluid limitation?*
>
> A. *Yes.*

ArthroCare did not introduce any contrary testimony, and did not even call its own expert Dr. Goldberg to testify in rebuttal to Smith & Nephew's invalidity case. And while ArthroCare did cross-examine Dr. Taylor on this issue, Dr. Taylor did not waver in his opinion that claim 1 of the Roos '198 patent disclosed the use of electrically conductive fluid. Indeed, the only admission that ArthroCare obtained from Dr. Taylor

was that the Roos '198 patent did not explicitly use either the word "saline" or the term "Lactated Ringer's." (Tr. at 1375) (D.I. 416). However, the Court has already ruled that electrically conductive fluid is not limited to saline or Lactated Ringer's, but instead includes "*any fluid* that facilitates the passage of electrical current" (emphasis added).

Accordingly, Smith & Nephew has established that the disclosure of "liquid to provide electrical conductance" in claim 1 of the Roos '198 patent was both highly material to the prosecution of the '592 patent and had been overlooked by the Examiner.

c. Mr. Raffle's Arguments to the Examiner

In his response to the Examiner's Office Action of February 29, 2000, Mr. Raffle took advantage of the fact that the Examiner had not reviewed claim 1 of the Roos '198 patent, and argued that Roos did *not* disclose the use of electrically conductive fluid (*see, e.g.*, DTX-301 at 22):

> Because the Roos '198 Patent does not disclose the use of electrically conductive fluid with any devices disclosed therein, it cannot anticipate any of the claims of this application.
>
> * * *
>
> The Roos '198 Patent does not state that the "washing liquid" that is supplied to the region of the surgical site is electrically conductive fluid.

There can be no dispute that when Mr. Raffle made these arguments to the PTO, he *knew* that they were wrong. In particular, when he was cross-examined at trial, Mr. Raffle squarely admitted that when he made these arguments to the Examiner, he *knew* about the disclosure of electrically conductive fluid, *i.e.*, "liquid to provide electrical conductance," in claim 1 of the Roos '198 patent, but did not tell the Examiner about what he knew (Tr. at 1516-17) (D.I. 417) (emphasis added):

> Q. Okay. You filed -- you prosecuted the '592 patent; correct?
>
> A. That's correct.
>
> Q. And you filed an office action to overcome a rejection in the '592 prosecution; right?
>
> A. I believe that's right.

* * *

Q. The rejection involved the Roos patent; right?

A. That's right.

Q. The examiner had rejected the Roos patent because -- rejected your claims on the Roos patent because he thought that the Roos patent just -- would teach a conductive fluid; right?

A. I think that's right.

Q. *And you told him that it didn't; right?*

A. *Yeah, that's right.*

Q. *And at the time you told him that, you knew that Claim 1 of the Roos patent said liquid to provide electrical conductfance]; right?*

A. *I was familiar with the Roos patent. Correct.*

Q. *And that's what you -- you did not tell him about Claim 1, did you?*

A. Specifically about Claim 1?

Q. Right.

A. *I don't believe so.*

Mr. Raffle not only knew about the disclosure of claim 1 of the Roos '198 patent, but he also knew two other highly material things. First, it is undisputed that he also knew that Judge Orrick had specifically found that claim 1 of the Roos '198 patent disclosed electrically conductive fluid in connection with his earlier Memorandum Decision and Order of December 1, 1998 in the *ArthroCare v. Ethicon* case (Exhibit D, at 17):[6]

> The Court finds that the Roos '198 patent and the Elsasser and Roos article describe a bipolar electrosurgery device intended to be used in electrically conductive fluid, with electrical current flowing between the active and return electrodes through the fluid.

[6] This Opinion was also cited in Smith & Nephew's Answer and Counterclaims (D.I. 10) at paragraphs 15-18, 22-23.

Second, Mr. Raffle further knew, particularly as it was discussed in Judge Orrick's opinion, that Mr. Roos had published a paper with Dr. Elsasser (DTX-59A, -59B, Exhibits E and F) describing the use of one of the devices from the Roos '198 patent in 32 successful surgeries, in which the irrigation liquid was explicitly described as facilitating the passage of electrical current (DTX-59B at 7) (emphasis added).[7]

> The high frequency current ... flows directly from the active cutting electrode, through the tissue to be cut *and the irrigation liquid*, to the annular neutral electrode at the proximal end of the resectoscope shaft.

Yet Mr. Raffle didn't tell the PTO any of this, and intentionally chose not to provide this information to the Examiner. Instead, in his Amendment in response to the Office Action, he devoted nearly 2 1/2 pages of argument in an attempt to misdirect the Examiner away from his conclusion that the Roos '198 patent "must" inherently disclose electrically conductive fluid. (DTX-301 at 22-25).

As part of that argument, he referred the PTO to another Roos patent, U.S. Patent No. 4,706,667 ("the '667 patent", PX-605, Exhibit G), and argued that the '667 patent proved that electrically conductive fluid was not used in the Roos '198 patent (DTX-301 at 23-24). But what he also knew, and what he also never told the Examiner, was that ArthroCare had made the same argument in the *ArthroCare v. Ethicon* case, and that argument had been rejected by Judge Orrick. (Memorandum Decision and Order of December 1, 1998, at 17, Exhibit D):

> The Court notes that the device described in the Roos '667 patent was a specific device that may not have embodied all of the disclosure of the Roos '198 patent.

He also knew that the Elsasser and Roos article was more relevant to the Roos' 198 patent than the Roos '667 patent was. The Elsasser and Roos article described the

[7] It was also undisputed at trial that the Elsasser and Roos article disclosed the use of electrically conductive fluid. (*See* Tr. at 1299). The only admission that ArthroCare obtained from Dr. Taylor is that the article does not use either the word "saline" or the term "Lactated Ringers." (Tr. 1375-77) (D.I. 416).

use of one of the embodiments of the Roos '198 patent in 32 successful surgeries. Specifically, Dr. Taylor explained the connection as follows (Tr. at 1365) (D.I. 416):

> Q. And in the Roos and Elsasser article, the instrument that was used was essentially the instrument from Figures 7 and 8 of the '198 patent; right? That's the one that was used to perform the surgery?
>
> A. That configuration was the one that was used to perform the surgeries. They also tried another configuration, and I have forgotten which figure it refers to in the patent, that worked but not as well.

Yet, instead of explaining to the Examiner what Judge Orrick had found, or the relationship between the Elsasser and Roos article and the Roos '198 patent, Mr. Raffle made arguments that were contrary to Judge Orrick's findings. As such, Mr. Raffle clearly had the duty to disclose Judge Orrick's opinion under MPEP 2001.06(c): "Another example of such material information is any assertion that is made during litigation which is contrary to assertions made to the examiner." *See, e.g., Marlow Industries, Inc. v. Igloo Products Corp.*, 2002 WL 485698, at *5-6 (N.D. Tex. March 28, 2002) (granting summary judgment of inequitable conduct for failure to disclose court opinions), *aff'd, Rule 47.6*, 2003 WL 21212626 (Fed. Cir. May 23, 2003); *Newell Window Furnishings, Inc. v. Springs Window Fashions Div., Inc.*, 1999 WL 1077882, at 29-31 (N.D. Ill. Oct. 7, 1999) (opinion denying preliminary injunction in related litigation found to be material), *rev'd on other grounds*, 15 Fed. Appx. 836 (Fed. Cir. 2001); *Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co., Inc.*, 837 F.Supp. 1444, 1477 (N.D. Ind. 1992).

However, with respect to Judge Orrick's opinion, Mr. Raffle simply listed the opinion as the 40th in a list of 84 items that the Examiner could get if he asked for it, without bothering to send it to the PTO (DTX-300 at 121-30, *see* page 125) (Exhibit H). As such, Mr. Raffle failed to provide "[e]nough information ... to clearly inform the Office of the nature of these issues so that the Office can intelligently evaluate the need for asking for further materials in the litigation" as is expressly required by MPEP 2001.06(c).

d. The PTO Relied on Mr. Raffle's Arguments

As a result of Mr. Raffle's arguments included in the Amendment mailed on May 25, 2000 (DTX-301 at 18-25), the Examiner withdrew his rejections based on the Roos '198 patent (DTX-301 at 331-34). Thus, it is clear that the Examiner relied on Mr. Raffle's arguments, and that Mr. Raffle's arguments were material even under the "but for" standard, which is the highest standard for materiality ever considered by the Federal Circuit. *See American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984).

e. ArthroCare's Arguments are Unavailing

ArthroCare has made three arguments in an attempt to overcome Smith & Nephew's showing of inequitable conduct in connection with the '592 patent. (D.I. 428). All are unavailing.

i. The Jury Verdict is Not Relevant

The jury verdict has no relevance to Smith & Nephew's inequitable conduct contentions. ArthroCare has argued that Mr. Raffle's failure to disclose claim 1 of the Roos '198 patent is not material in light of the jury's verdict. (D.I. 428 at 7). ArthroCare may make the same argument with respect to Mr. Raffle's failure to discuss the Elsaaser and Roos article. However, such arguments have no merit, for at least the following three reasons:

First of all, as fact finder for the inequitable conduct portion of the case, this Court has the obligation to evaluate the materiality of the withheld information independently. This is even more so where, as here, ArthroCare opposed submitting the question of inequitable conduct to the jury in its Motion *in Limine*. (D.I. 322). Further, the jury was not even instructed on the law relating to materiality or any portion of inequitable conduct.

Second, there is no way to know on what basis the jury made its decision. As set forth above, ArthroCare introduced no rebuttal evidence regarding the disclosure of

electrically conducting fluid in the Roos '198 patent, and Dr. Taylor did not waver with respect to his opinion during his cross-examination. Indeed, based on ArthroCare's cross-examination of Dr. Taylor, it appears that ArthroCare was trying to suggest that the Roos '198 patent did not disclose a "connector." (Tr. at 1370-72) (D.I. 416). Thus, the jury might well have decided that the Roos '198 patent did not anticipate the '536 patent because of lack of a connector.[8]

Finally, it is well settled that the standards for anticipation and materiality are different, and that a reference need not anticipate in order to be material. *See, e.g.*, *PerSeptive Biosystems*, 225 F.3d at 1322 (stating that a patent may be valid and yet be rendered unenforceable due to inequitable conduct); *Molins PLC*, 48 F.3d at 1182 ("We recognize that [the withheld references] were cited eventually to the PTO and that the examiner initialed them and passed the reexamination application to issue thereafter. However, the references were not cited when they should have been.").

ii. The "Same Examiner" Argument is a Red-Herring

ArthroCare has also argued that there was no need to tell the Examiner about the disclosure of claim 1 of the Roos '198 patent, since the same Examiner that was considering the '592 application had also examined the Roos '198 patent. (D.I. 428 at 8 n.2). However, what ArthroCare fails to point out is that *23 years* had transpired since Examiner Cohen examined the Roos '198 patent, so there was no way to expect him to remember one line from a claim he had reviewed 23 years earlier.

In any event, at trial, Mr. Raffle squarely admitted that when he decided that he was not going to tell the Examiner about what was in claim 1 of the Roos '198 patent, he

[8] In view of the Court's interpretation of the term "connector" as "a structure that electrically links the electrode terminal to the high frequency power supply," (4/9/03 Memorandum Order at 2) (D.I. 353), ArthroCare's cross-examination of Dr. Taylor on this point was clearly intended to confuse and mislead the jury, since all RF devices would need to have such a connector to work.

did not base his decision on the fact that he was dealing with the same Examiner who examined the Roos '198 patent (Tr. 1541) (D.I. 417):

> Q. Okay. Examiner Cohen reviewed the application for the Roos '198 patent 23 years before the prosecution of the '592 patent; right?
>
> A. That might be. I don't remember the issue date of the Roos. That could be right.
>
> Q. When you decided that you weren't going to tell him about what was in Claim 1 of the Roos patent, did you have in mind that he must remember this 23 years later?
>
> MR. BLUMENFELD: Objection, your Honor.
>
> THE WITNESS: No.

iii. The Decision in the '536 Reexamination is Not Relevant

ArthroCare also argues that "four Patent Office examiners" have considered the Roos '198 patent, citing to the reexamination of the '536 patent. (D.I. 428 at 7). This argument is also not relevant. As we will show in the next section, there is no evidence that any one of those Examiners ever considered claim 1 of the Roos '198 patent.

f. Materiality

As shown above, the teaching of "liquid to provide electrical conductance" in claim 1 of the Roos '198 patent was highly material to the examination of the '592 patent. In addition, the Elsasser and Roos article and Judge Orrick's opinion -- which found that both the Roos '198 patent and the Elsasser and Roos article disclosed electrically conductive fluid -- were both also highly material. This information was material under any applicable standard, particularly in view of Mr. Raffle's contrary arguments. All of this information clearly meets the materiality requirements of the current version of 37 C.F.R. § 1.56(b)(2)(ii) since it "refutes, or is inconsistent with, a position the applicant takes in … (ii) Asserting an argument of patentability." Indeed, by arguing as he did without submitting this contrary information Mr. Raffle clearly also violated MPEP 2001.06(c).

g. Intent to Mislead or Deceive

Accordingly, since Smith & Nephew has established that the "withheld information is material and the patentee knew or should have known of that materiality," there is an inference of intent to mislead, and ArthroCare and Mr. Raffle "can expect to have great difficulty in establishing subjective good faith sufficient to overcome [that] inference of intent to mislead." *Bristol-Myers Squibb*, 326 F.3d at 1239. Indeed here, as in *Bristol-Myers Squibb*, the requisite intent to mislead can be inferred simply from the facts that (a) Mr. Raffle knew of the significance of the withheld information, and (b) also knew of the duty to disclose. *Id.* 326 F.3d at 1240.

Thus, inequitable conduct in connection with the '592 patent is clear, and the '592 patent is unenforceable.

2. ArthroCare's Inequitable Conduct In Connection with the '536 Patent

With respect to the reexamination of the '536 patent, ArthroCare committed two types of inequitable conduct. The first relates to ArthroCare's failure to disclose Smith & Nephew's summary judgment briefs relating to the issue of invalidity, the Taylor expert report on invalidity and the Roos Declaration, as required by MPEP 2001.06(c).

The second is closely related to ArthroCare's inequitable conduct during prosecution of the '592 patent, and ArthroCare's arguments in overcoming the Roos '198 patent during such prosecution. In particular, this relates to Mr. Raffle's numerous off-the-record telephone conversations with the Examiner regarding the merits of the reexamination before a first Office Action on the merits and without filing timely interview summaries, all in clear violation of the applicable PTO rules.

With respect to the second ground for inequitable conduct, as discussed above, Smith & Nephew is seeking leave to take the deposition of the Examiner in the reexamination, Examiner Mendez, to determine the contents of these off-the-record communications. It is known that these off-the-record communications involved the

merits of the Roos '198 patent, and it is believed that in these off-the-record communications, Mr. Raffle may have convinced the Examiner to simply parrot back the arguments that Mr. Raffle had previously made with respect to the Roos '198 patent during prosecution of the '592 patent without performing any independent analysis.

a. The Duty to Disclose Information from Litigation

Prosecution of the reexamination of the '536 patent took place during the pendency of this lawsuit. Accordingly, the provisions of MPEP 2001.06(c) clearly apply MPEP 2001.06(c) specifies that "any assertion that is made during litigation which is contradictory to assertions made to the examiner" is material, and must be disclosed:

> **Information From Related Litigation**
>
> Where the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the U.S. Patent and Trademark Office. Examples of such material information include evidence of possible prior public use or sales, questions of inventorship, prior art, allegations of "fraud," "inequitable conduct," and "violation of duty of disclosure." Another example of such material information is any assertion that is made during litigation which is contradictory to assertions made to the examiner. *Environ Prods., Inc. v. Total Containment, Inc.*, 43 USPQ2d 1288, 1291 (E.D. Pa. 1997). Such information might arise during litigation in, for example, pleadings, admissions, discovery including interrogatories, depositions, and other documents and testimony.
>
> * * *
>
> Enough information should be submitted to clearly inform the Office of the nature of these issues so that the Office can intelligently evaluate the need for asking for further materials in the litigation.

MPEP 2001.06(c)

The knowing violation of MPEP § 2001.06(c) constitutes inequitable conduct. *See Boerunger Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F.Supp2d 508, 549 (D.N.J. 1999) ("[A]though the opinions addressing inequitable conduct allegations based upon information gathered in related litigation are few in number, the opinions teach clearly that Rule 56 and traditional inequitable conduct law apply to information

gathered from related litigation").[9] Here, there is no question that both (a) ArthroCare and its representatives, including Mr. Raffle, knew about the requirements of MPEP 2001.06(c), and (b) violated MPEP 2001.06(c).

b. Knowledge of MPEP 2001.06(c)

First of all, ArthroCare's in-house patent attorney, Mr. Raffle, is already on record as knowing about the requirements of MPEP 2001.06(c). In particular, in connection with the previous '592 prosecution, Mr. Raffle filed a paper in the PTO explaining that a competitor had brought MPEP 2001.06(c) to his attention, and that he was submitting information to the PTO in accordance with the requirements of MPEP 2001.06(c). (DTX-300 at 122, Exhibit H).

Moreover, other representatives of ArthroCare, including its trial attorneys in this case, were also aware of the requirements of MPEP 2001.06(c). In particular, during the hearing on November 7, 2002, Smith & Nephew's counsel brought the requirements of the MPEP to the attention of ArthroCare's trial counsel (11/7/02 Hearing Tr. at 8-9) (D.I. 185):

> What happened here is that in the course of the reexamination, ArthroCare took all of the 73 prior art references that we cited and they also took the very first invalidity [ch]art that we served on the[m] and they sent it into the Patent Office. Now, there is a rule that requires this. It's in the MPEP as Rule 2001.1 [sic] and they sent it to them.
>
> Now, I should also mention in terms of what is going to happen in the future in the reexam. We have, since that initial invalidity chart, we have supplemented our invalidity contentions twice including with some new art that we discovered in the course of the case and because of that same rule, ArthroCare is required to submit that information to the Examiner as well so he'll review that and he could well come up with additional rejections.

However, during trial, Mr. Raffle squarely admitted that he did not submit Smith & Nephew's expert reports or summary judgment motions on invalidity (Tr. at 1542) (D.I. 417):

[9] "Although MPEP § 2001.06(c) is not binding law, it is a useful tool to inform the Court of the [USPTO's] official interpretation of 1.56(b) regarding information brought to light during litigation." *Id.* at 548.

> Q. Finally, with respect to material that you did and did not submit to the Patent Office in connection with the re-exam, it is true, isn't it, that you did not submit Smith & Nephew's arguments about validity as set forth in its expert reports, Dr. Taylor's expert report, or in its summary judgment motions; right?
>
> MR. BLUMENFELD: Objection, your Honor.
>
> THE WITNESS: That's correct. We did not submit the expert reports in [sic: and] the summary judgment motions.

c. Failure to Disclose Relevant Information from Litigation

Neither ArthroCare nor Mr. Raffle submitted Smith & Nephew's summary judgment briefs relating to the issue of invalidity (D.I. 258, 262, 283, 300, 302) or Dr. Taylor's expert report on the issue of invalidity (Exhibit I) (*see, e.g.*, Marsden Dec., Ex. 1, D.I. 264). Nor did ArthroCare submit the Declaration of Eberhard Roos (Exhibit J) that was submitted with Smith & Nephew's summary judgment motions (*see. e.g.*, Marsden Dec., Ex. 8, D.I. 267). Such information would have allowed the PTO to fully comprehend Smith & Nephew's invalidity contentions, particularly since they included far more detailed explanations of the prior art than anything that ArthroCare submitted. The Roos Declaration in particular would have been highly material in the reexamination in accordance with MPEP 2258(I)(E): "Affidavits or declarations which explain the contents … of prior patents or printed publications in more detail may be considered in reexamination. …"

d. ArthroCare's Confidentiality Excuse is Unavailing

ArthroCare has offered as an excuse for failing to disclose Smith & Nephew's expert reports and summary judgment briefs that those briefs were designated as confidential. (D.I. 428 at 11-12). Such an argument is not an excuse at all. In fact, ArthroCare's admission that it intentionally withheld the expert reports and summary judgment briefs on this ground instead actually demonstrates its intent to deceive in connection with the '536 reexamination. The fact that certain of Smith & Nephew's expert reports and summary judgment briefs were marked confidential does not offer

ArthroCare an excuse for failing to disclose the reports and briefs for at least the following five reasons:

(1) Not all of Smith & Nephew's expert reports were marked as confidential. The expert reports from Drs. Choti and Manwaring on the issue of invalidity were not marked as confidential. (Exhibits K and L respectively). When ArthroCare was deciding to withhold Dr. Taylor's expert report on the ground of confidentiality, it must have realized that the other expert reports were not confidential. Accordingly, the only inference to be drawn is that ArthroCare willfully and intentionally withheld that material from the Patent Office.

(2) In addition, the *only* information included within Dr. Taylor's expert report and Smith & Nephew's summary judgment briefs relating to invalidity that was confidential, was *confidential to ArthroCare*, not to Smith & Nephew. Accordingly, it was entirely up to ArthroCare's own decision as to whether or not it would disclose this information to the PTO. Clearly, ArthroCare would not have violated this Court's Stipulated Protective Order by fulfilling its duties of disclosure to submit its own information to the PTO.

(3) If ArthroCare had any doubt about whose confidential information was contained in the Taylor expert report and Smith & Nephew's summary judgment briefs, ArthroCare could have easily contacted Smith & Nephew to see if Smith & Nephew would consent to such disclosure. Of course, had ArthroCare contacted Smith & Nephew, Smith & Nephew would have explained that the only confidential information in those papers belonged to ArthroCare, and ArthroCare was of course free to disclose it to the PTO. In addition, ArthroCare also could have approached the Court if it had any uncertainty for a modification of the Protective Order. The Stipulated Protective Order in this case specifically permits the parties to file motions to seek such modification. (D.I. 40, ¶ 25).

(4) Of course, even with respect to the Taylor expert report and Smith & Nephew's summary judgment briefs, ArthroCare could have disclosed the portions that were not confidential, including, for example, the Roos Declaration. (Exhibit J).

(5) Finally, it should be noted that ArthroCare had no problem submitting Smith & Nephew's confidential information to the Patent Office in connection with the reexamination (*see, e.g.*, PX-7 at 277-78) (Exhibit M), so it really has no excuse for failing to submit its own confidential information.

e. Mr. Raffle's Off-The-Record Interviews

As the Court is already aware, Mr. Raffle had numerous "off-the-record" discussions with Examiner Mendez during prosecution of the '536 reexamination. (*See, e.g.*, D.I. 177 at 8-9, 15-19; D.I. 217). These off-the-record discussions were in clear violation of 37 C.F.R. § 1.560(a) and MPEP 2281, since they took place before a first Office Action on the merits. These discussions were also not summarized as required by 37 C.F.R. § 1.560(b) and MPEP 2281. The short "Statement" filed by ArthroCare (PX-7 at 228-30), certainly does not comply with the rule.

At this point, since Mr. Raffle had little memory about his conversations with the Examiner during his deposition, there is no way of knowing what Mr. Raffle said to the Examiner, unless Smith & Nephew is allowed to take the Examiner's deposition. All that is known is that *after* he spoke with Mr. Raffle, Examiner Mendez issued an Office Action in which he essentially parroted-back, verbatim, the entirety of Mr. Raffle's arguments made to Examiner Cohen during the earlier prosecution of the '592 patent. (Compare, PX-7 at 216-220 with DTX-301 at 22-25).[10]

It is clear, however, that Mr. Raffle once again did not *discuss* claim 1 of the Roos '198 patent with the Examiner during these discussions. Had he done so, surely the Examiner would have mentioned it, and explained why "liquid to provide electrical

[10] Also, see Exhibit P, which is the side-by-side comparison presented to Mr. Raffle during trial (Tr. at 1517-20) (D.I. 417), with the minor changes made by the Examiner to Mr. Raffle's arguments highlighted in yellow.

conductance" was not "electrically conducting fluid." However, claim 1 of the Roos '198 patent has never been mentioned in any paper issued by any Examiner in connection with the '536 reexamination, and accordingly, was never disclosed by Mr. Raffle.

In order to permit Smith & Nephew to determine just what was said by Mr Raffle, the Court should grant Smith & Nephew leave to take Examiner Mendez' deposition.

f. Materiality

A Court must analyze information generated in litigation and determine whether that information was material to the pending application. *Boehringer*, 68 F.Supp.2d 548. The fact that ArthroCare provided some material information, the prior art, to the PTO does not preclude the possibility that the parties' arguments and expert opinions might also be material non-cumulative information under Rule 56(b). *Id.* at 550. Information is material when "[i]t refutes, or is inconsistent with, a position the applicant takes in (i) [o]pposing an argument of unpatentability relied on by the [Patent] Office, or (ii) [a]sserting an argument of patentability." 37 C.F.R. § 1.56(b)(2)(i)-(ii).

Smith & Nephew's expert reports and its summary judgment briefs on the issues of invalidity clearly constitute material information required to be disclosed under M.P.E.P. 2001.06(c). For example, Smith & Nephew's Opening Brief in Support of Its Motion for Summary Judgment of Invalidity Based on Prior Art (35 U.S.C. §§ 102 and 103) (D.I. 262) refutes the position ArthroCare took regarding the patentability of the claims of the '536 patent over the Roos '198 and other prior art references. During the prosecution of the '536 patent reexamination, ArthroCare argued for patentability over these references (PX-7 at 231-54). Smith & Nephew's summary judgment briefs and expert reports refute the patentability arguments made by ArthroCare. Therefore, these documents are clearly material and should have been submitted under MPEP §2001.06(c).

g. Intent to Mislead or Deceive

After analyzing the materiality of the prior litigation and ArthroCare's counsel's knowledge of its obligation to and failure to cite these material litigation documents, the next inquiry is whether there is a sufficient level of intent. *Boehringer*, 68 F. Supp.2d. at 550. ArthroCare's intent to mislead should be inferred from its limited disclosure of the present litigation and its failure to share highly material litigation documents with the PTO. *Id.* at 551 ("because Boehringer failed to disclose the arguments raised and the outcome of the preliminary injunction and summary judgment proceedings, an inference of deceptive intent on Boehringer's part sufficient to establish the substantial merit of Schering's defense may be inferred.")

Accordingly, the '536 patent should be found unenforceable due to inequitable conduct.

3. ArthroCare's Inequitable Conduct In Connection with the '882 Patent

Smith & Nephew's inequitable conduct contentions with respect to the '882 patent relate to the circumstances under which ArthroCare obtained the Certificate of Correction for claim 1 of the '882 patent.

This is the Certificate of Correction that changed the scope of claim 1 of the '882 patent by broadening the claim to reduce the number of electrodes that were required by the claim. Prior to the Certificate of Correction, claim 1 of the '882 patent required four electrodes: an electrode terminal, an active electrode, a return electrode, and an electrically conducting terminal. (JTX-2 at col. 24 lines 8-12, Exhibit N). However, after the Certificate of Correction, the claim required only two electrodes: an electrode terminal and a return electrode. (*See* Certificate of Correction attached to JTX-2). It was undisputed at trial that if the Certificate of Correction had not been obtained (or was invalid) Smith & Nephew would not infringe the '882 patent. (*See* testimony of ArthroCare's expert, Dr. Goldberg, (Tr. 1110) (D.I. 415)).

Mr. Raffle was seeking the Certificate of Correction in order to file suit against Ethicon. In obtaining the Certificate of Correction, Mr. Raffle made at least two affirmative misrepresentations, and also failed to explain how the so-called "correction" would broaden the claim when he clearly had a duty to do so. These inequitable conduct contentions are supported by the trial testimony of both Mr. Raffle and ArthroCare's expert Dr. Goldberg, as well as the file history for the '882 patent.

a. Facts Relating to '882 Prosecution

On December 17, 1997, Mr. Raffle, as ArthroCare's in-house patent attorney, submitted a Request for Certificate of Correction Under 37 CFR § 1.323. (DTX-306 at 234-35, Exhibit O). In that Request, Mr. Raffle sought to make changes to "claim 23" of the '882 patent. (*Id*).[11] In his Request for Certificate of Correction, Mr. Raffle made two key factual assertions which were shown to be *false* during the trial. Mr. Raffle also failed to explain how the so-called "correction" that he was seeking would broaden the scope of the claim, despite the fact that the Examiner had expressly relied on the narrow scope of the claim when he decided to allow the patent.

b. Mr. Raffle's First Misrepresentation

First of all, and as support for his argument that the changes he was seeking in the Certificate of Correction only involved correction of "typographical errors," Mr. Raffle falsely asserted that "[a]pplicant amended all of the claims to replace the term 'active electrode' with 'electrode terminal.'" (*Id.*). However, at trial, Mr. Raffle squarely admitted that this assertion was untrue. In particular, when confronted with the amendments he made to application claim 52 (which became patent claim 26) at the same

[11] Mr. Raffle was using an incorrect claim number. In a subsequent paper he filed on April 20, 1998, Mr. Raffle made clear that when he requested a correction to claim 23, he actually meant to request a correction to claim 1 instead. (DTX-306 at 239). Apparently, Mr. Raffle was referring to the application claim number, rather than the issued claim number, when he filed his Request for Certificate of Correction, since, as Mr. Raffle testified at trial, application claim no. 23 became issued claim 1 of the '882 patent. (Tr. at 1510) (D.I. 417). Thus, it should be clear that in Mr. Raffle's Request for Certificate of Correction Under 37 CFR § 1.323 which was filed on December 17, 1997, he was actually seeking to change claim 1 of the '882 patent not claim 23.

time that he amended application claim 23 (which became patent claim 1), Mr. Raffle was forced to admit that he in fact did not amend application claim 52 to replace "active electrode" with "electrode terminal" (Tr. 1511-1513) (D.I. 417) as he had told the PTO in his Request for Certificate of Correction.

The Request for Certificate of Correction alleges that the errors being corrected arose in connection with an amendment that Mr. Raffle filed during prosecution of the application for the '882 patent on March 25, 1997. Accordingly, it is useful to review that amendment. The amendment is included in DTX-306 at 200-10. (Exhibit O). For purposes of the inequitable conduct issue, it is useful to compare Mr. Raffle's amendment of application claim 23 (which became patent claim 1) with his amendment of application claim 52 (which became patent claim 26).[12] As can be seen, Mr. Raffle amended the claims that would become claims 1 and 26 so that they both included an "active electrode," a "return electrode," and an "electrode terminal." He admitted to this at trial (Tr. 1511-13) (D.I. 417):

> Q. Mr. Raffle, on Pages 204 and 205, there is the claim that became Claim 26 of the issued patent; correct?
>
> A. Yes.
>
> Q. And at the same time, you made the changes to Claim 1, you also made changes to Claim 26; right?
>
> A. Yes.
>
> * * *
>
> Q. Now, in this claim you also left in the terms active electrode in the third line of the claim that became Claim 26; is that right?
>
> A. Yes, that's right.
>
> * * *

[12] A side-by-side comparison of Mr. Raffle's amendments to application claims 23 and 52 (which became patent claims 1 and 26 respectively) was used to cross-examine Mr. Raffle at trial. For the convenience of the Court, that comparison is included as Exhibit P.

Q. So just to review, in Claim 1, in the second -- in the third line, you changed active electrode to electrode terminal, right?

A. Yes.

Q. And in the third line of Claim 26, you left active electrode all alone. You didn't change it; right?

A. That's correct.

Q. Okay. And then in the sixth line of Claim 1, you left active electrode again all alone, didn't change it; right?

A. Correct.

Q. And in the corresponding sixth line of Claim 26, you changed active electrode to electrode terminal; right?

A. Correct.

There can be no doubt that Mr. Raffle *knew* that his statement in the Request for Certificate of Correction that "Applicant amended all of the claims to replace the term 'active electrode' with 'electrode terminal'" (DTX-306 at 234) was false. Indeed, when he filed his Request for Certificate of Correction, Mr. Raffle expressly represented that he had reviewed *all* of the "rest of the independent claims in this application" *including* claim 52 (which became patent claim 26). Moreover, when confronted with the fact that he did not change "active electrode" to "electrode terminal" at trial, Mr. Raffle expressed no surprise whatsoever. (Tr. at 1512) (D.I. 417).

c. Mr. Raffle's Second Misrepresentation

Mr. Raffle's Second Misrepresentation was a little more subtle. One of the requirements for a Certificate of Correction is that the error sought to be corrected must be clear. *See Superior Fireplace Co. v. Majestic Products Co.*, 270 F.3d 1358, 1370, 1372 (Fed. Cir. 2001). In an apparent effort to show that the error he sought to correct was clear, Mr. Raffle explained that there was an error in the antecedent basis for application claim 23 (DTX-306 at 234):

> This term on line 5 derives antecedent basis from "an electrode terminal" on line 3 (also note the reference to electrode terminal on lines 7 and 9 of claim 23). Accordingly, in order to correct this error in

antecedent basis, Applicant wishes to change "active electrode" on line 5 to "electrode terminal."

However, what Mr. Raffle did not point out to the PTO was that there were other instances in the claims of the '882 patent in which there was an improper antecedent basis *which were acceptable to ArthroCare*.

For example, during trial Mr. Raffle admitted that application claim 52 (which became issued claim 26) also included an improper antecedent basis, yet ArthroCare never sought a Certificate of Correction for that claim (Tr. 1541) (D.I. 417):

Q. On the certificate of correction, you did not ask to change Claim 26, right?

A. I believe that's correct, yes. Claim 26.

Q. As issued.

A. As issued. That's correct.

Q. You did not ask to correct that?

A. That's correct.

And as discussed above, it is clear that Mr. Raffle reviewed application claim 52 when he filed his Request for Certificate of Correction, because he expressly told the PTO that he did. (DTX-306 at 235).

d. Mr. Raffle's Omission

Finally, Mr. Raffle also committed inequitable conduct when he failed to explain that the Certificate of Correction would broaden the scope of the claim, despite the fact that he knew the Examiner had relied on the scope of the "uncorrected" claim when he decided to allow the patent to issue.

As is not uncommon, the Examiner provided a statement of his reasons for allowing the '882 patent to issue, which relied on the scope of application claim 23 as of June 22, 1997 -- i.e., before it was broadened by Mr. Raffle's Certificate of Correction (DTX-306 at 222):

The following is an examiner's statement of reasons for allowance: The prior art of record does not disclose or suggest a method for applying

> energy to a target site on a patient body structure comprising providing an electrode terminal and a re m electrode electrically coupled to a high frequency voltage source; positioning the active electrode in close proximity to the target site in the presence of an electrically conducting terminal; and, applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

As can be seen, the Examiner's Reasons for Allowance was clearly based on the "uncorrected" scope of application claim 23 as it essentially quotes that claim (compare the Reasons for Allowance with application claim 23 as set forth in the Amendment of March 25, 1997, DTX-306 at 201). Such a statement of Reasons for Allowance is "absolutely binding on the patentee, absent an objection by the patentee thereto." *Apex Inc. v. Raritan Computer, Inc.*, 187 F.Supp.2d 141, 155 (S.D.N.Y. 2002).

There can be no serious dispute that Mr. Raffle had received and was aware of the statement of Reasons for Allowance. First of all, Mr. Raffle was the attorney of record for the application. (*See, e.g.*, DTX-306 at 220). Second, the statement of Reasons for Allowance was attached to the Notice of Allowability which was sent to Mr. Raffle. (*See* DTX-306 at 221).

The statement of Reasons for Allowance included an invitation for comments or questions (DTX-306 at 222-23), but none were ever filed by Mr. Raffle. Instead of filing an objection to the statement of Reasons for Allowance, or pointing out that the Examiner's Reasons for Allowance was dependent on alleged "typographical errors" -- as any reasonable patent attorney would do if there really were typographical errors -- Mr. Raffle simply filed his Request for Certificate of Correction and never once mentioned that he was changing the scope of claim 1.

The Examiner obviously relied on Mr. Raffle's omission. In particular, in his Notes Re: Certificate of Correction, the Examiner checked the box marked "no" to the question that asked whether the changes would "[m]aterially affect the scope or meaning of the claims allowed by the examiner in the patent." (DTX-306 at 227). Clearly, if Mr.

Raffle had told the truth -- if Mr. Raffle had explained that the changes *would* affect the scope of the claim -- the Examiner would not have approved the Certificate of Correction as he did.

Throughout the pendency of this case, realizing that the Examiner had relied on Mr. Raffle's failure to tell the PTO that the Certificate of Correction changed the scope of claim, ArthroCare has strenuously argued that the Certificate of Correction did not change the scope of the claim. For example, during the hearing on claim construction and summary judgment held on April 1, 2003, ArthroCare's counsel argued that the Certificate of Correction did not broaden the claim. (Tr. at 163-64) (D.I. 335).

However, during the trial, ArthroCare's expert, Dr. Goldberg, squarely admitted that the Certificate of Correction did in fact broaden the scope of claim 1 of the '882 patent, contrary to the positions taken by ArthroCare (Tr. 1109-11) (D.I. 415):

Q. ... This is Claim 1 of the '882 patent as it issued; correct?

A. I believe -- yes, sir, that's correct.

Q. And as it issued, the claim required an electrode terminal, a return electrode, the active electrode and an electrically conducting terminal; right?

A. Those are the words in the finally printed original patent, sir.

Q. Those are four different electrodes in the printed patent; right?

A. At least three, sir.

Q. At least three? At least three, maybe four?

A. Yes, sir.

* * *

Q. ... Requiring three or four electrodes makes the claim narrower than requiring only two electrodes; right?

A. It would make it stricter to fulfill the criteria, yes.

Q. Stricter to fulfill [is] the same as narrower?

A. Yes.

e. Mr. Raffle's Motives

At the time that Mr. Raffle filed his first Request for Certificate of Correction, ArthroCare was preparing to file suit against Ethicon for infringement of several patents, including the '882 patent. ArthroCare in fact filed its lawsuit against Ethicon on February 13, 1998,[13] less than two months after Mr. Raffle filed his initial Request for Certificate of Correction. Indeed, it was apparently the pressure of the impending lawsuit that caused Mr. Raffle to (a) file his Request for Certificate of Correction on the day after the '882 patent issued, and (b) erroneously refer to application claim 23 rather than patent claim 1, as discussed above. Indeed, it was not until April 20, 1998, after the *ArthroCare v. Ethicon* case was well under way, that Mr. Raffle filed for a Certificate of Correction which referred to the correct claim number (claim 1, rather than claim 23). (*See* DTX-306 at 239).

Claim 1 of the '882 patent was obviously an important claim for Mr. Raffle in connection with ArthroCare's lawsuit against Ethicon. Claim 1 of the '882 patent was one of only eight total claims (from four patents) that ArthroCare asserted against Ethicon. (*See* Judge Orrick's Memorandum Decision and Order of December 1, 1998 in *ArthroCare v. Ethicon*, Exhibit D, at 2).

f. Materiality

Materiality of the information that was misrepresented or omitted by Mr. Raffle is beyond dispute. Had Mr. Raffle told the PTO that his Certificate of Correction would actually broaden the claim, and was contrary to the Examiner's statement of Reasons for Allowance, the Certificate of Correction clearly would not have issued. Similarly, had Mr. Raffle told the PTO that at the very same time he made what he now calls "typographical errors" in application claim 23, he determined that the very same kind of

[13] A copy of the Complaint from the *ArthroCare v. Ethicon* case is attached as Exhibit Q and a copy of the docket from that case is attached as Exhibit K. Smith & Nephew asks the Court to take judicial notice of these facts.

so-called "errors" in application claim 52 were acceptable, the Certificate of Correction would not have issued.

g. Intent to Mislead or Deceive

As is typical in cases in which inequitable conduct is found, the intent to deceive here may be inferred from the surrounding circumstances. *Bristol-Myers Squibb*, 326 F.3d at 1239 ("Intent to mislead does not require direct evidence, and is typically inferred from the facts."); *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 882 F.2d 1556, 1562 (Fed. Cir. 1989).

Here, Mr. Raffle was clearly trying to broaden claim 1 of the '882 patent so that ArthroCare could file its impending lawsuit against Ethicon. Further, his attempts succeeded in obtaining a Certificate of Correction that in fact broadened claim 1 of the '882 patent. In *General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405 (Fed. Cir. 1994), the Federal Circuit held that "as a matter of law [ ] a false statement in a petition to make special is material if, as in this case here, it succeeds in prompting expedited consideration of the application." *Id.* at 1411. In the present case, the Certificate of Correction is even more material than the petition to make special. First, a petition to make special merely impacts the procedural working of the PTO. Second, and more importantly, a Certificate of Correction is closely related to the validity of the patents-in-suit. As such, ArthroCare's mere denial of its intent to mislead the PTO is not sufficient to overcome the strong materiality of Mr. Raffle's omissions. *Id.* at 1411.

Accordingly, the '882 patent should be declared unenforceable due to inequitable conduct.

C. ArthroCare's Inequitable Conduct In Connection with Any One or Two Of the Patents Taints the Other Patent(s)

The Federal Circuit has identified a two-factor test for finding related patents unenforceable: (1) inequitable conduct or unconscionability exists and (2) the inequitable conduct had a direct "relation" to the requested relief. *Consolidated Aluminum v. Foseco*

International, 910 F.2d 804, 810 (Fed. Cir. 1990) (citing *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933)). In *Consolidated Aluminum*, the Federal Circuit found inequitable conduct sufficient for the court to hold all of the patents-in-suit unenforceable because the conduct at issue had a direct relationship to those patents. *Id.* at 812. The court noted that the prosecution histories of the patents-in-suit were intertwined and that two of the patents were continuations-in-part of the third patent. *Id.*

As in *Consolidated Aluminum*, the patents-in-suit in the present case are closely related such that a finding of inequitable conduct during the prosecution of the '592 patent, the '882 patent or the '536 reexamination would render all three patents-in-suit unenforceable. First and foremost, the patents are genealogically related descendants of the same original patent applications. The three patents share the same inventors, relate to the same electrosurgical system, have been licensed together, and were asserted together in this litigation.

In addition, the conduct at issue with regard to the '592 and '882 patents and the '536 reexamination bears an "immediate and necessary relation" to the equity sought by the patentee, namely the enforcement of the other patents-in-suit, to render them similarly unenforceable. *Id.* at 811-12. The patents-in-suit are so closely related that prior art relevant to any one of these is clearly relevant to each of the others. Likewise any misrepresentation made regarding a prior art reference or the scope of the claims in the prosecution of one patent could have an impact on the other two.

Moreover, all three patents share common claim terms. Thus, any argument by ArthroCare or statement by the Examiner that may have been made but for ArthroCare's inequitable conduct, would necessarily affect the other two patents as well.

1. **ArthroCare's Inequitable Conduct In Connection With The '592 Patent Taints the Enforceability of the Other Patents-in-Suit**

ArthroCare's misrepresentations to the PTO regarding the disclosure of the prior art Roos '198 patent during the prosecution of the '592 patent is related to the validity of

both the '882 and '536 patent. Specifically, to the extent that ArthroCare's conduct misrepresents the significance of the Roos '198 patent as prior art to the '592 patent, this conduct also misrepresents the significance of this art to the other two patents, makes it less likely that the other two patents will be subject to reexamination, and has the potential to impact or taint any reexamination proceeding that may occur for either of these patents. This is exactly what in fact happened with respect to the '536 patent, and could happen with respect to the '882 patent.

ArthroCare's misrepresentations regarding the Roos '198 patent were made in an argument for patentability in an office action response during the prosecution of the '592 patent. This multi-page argument also appears in the '536 reexamination almost verbatim in an office action filed by the Examiner despite the fact that the argument is not made in any recorded ArthroCare submission during the reexamination. (Exhibit S) (Tr. 1516-1521) (D.I. 417). An Examiner's use of ArthroCare's earlier misrepresentations and arguments from the '592 patent prosecution shows that these misrepresentations are also directly related to the '536 reexamination and in fact had an impact on those proceedings, and could well have a similar impact with respect to proceedings concerning the '882 patent.

Moreover, had ArthroCare disclosed the language of claim 1 of the Roos '198 patent as it was required to do, the ensuing prosecution could well have affected the interpretation of "electrically conductive fluid," a claim element which also appears in the '882 and '536 patents as well.

A finding of inequitable conduct during the prosecution of the '592 patent should render all three patents-in-suit unenforceable.

2. **ArthroCare's Inequitable Conduct In Connection With The '536 Patent Taints the Enforceability of the Other Patents-in-Suit**

ArthroCare's inequitable conduct during the reexamination of the '536 patent also is related to and taints the validity of the other patents-in-suit. ArthroCare's failure to

provide the PTO with relevant litigation-related documents concern all of the patents-in-suit. These documents provide relevant information concerning the prior art references material to all three of the patents-in-suit that could affect the validity of the claims of any or all of the three patents-in-suit. For example, Smith & Nephew's Opening Brief in Support of Its Motion for Summary Judgment of Invalidity Based on Prior Art (35 U.S.C. §§ 102 and 103) (D.I. 262) provides material arguments regarding the validity of the claims of all three patents-in-suit over various prior art references.

Misrepresentations and omissions relating to prior art in the proceedings of one patent taints the validity of closely related patents when such prior art is also relevant to the claims of the closely related patents. Here, the arguments made by ArthroCare relate to many of the claim terms that appear in the '592 and '882 patents as well. ArthroCare's violation of MPEP 2001.06(c) hid material information regarding prior art disclosures relevant to all three patents-in-suit, the scope of the claims of all three patents-in-suit, and the meaning of many terms common to all three patents-in-suit.

A finding of inequitable conduct during the prosecution of the '536 reexamination should render all three patents-in-suit unenforceable.

3. ArthroCare's Inequitable Conduct In Connection With The '882 Patent Taints the Enforceability of the Other Patents-in-Suit

Finally, ArthroCare's inequitable conduct during the examination of the '882 patent also is related to and taints the validity of the other patents-in-suit. ArthroCare's misrepresentations and omissions relating to the Certificate of Correction in the '882 patent constitute inequitable conduct as described above. These misrepresentations and omissions are related to the claims of the '592 and '536 patents. Specifically, they relate to the meaning of the terms "active electrode" and "electrode terminal" used in all three of the patents-in-suit. Any change in the prosecution which might affect the interpretation of either of these claim terms in the '882 patent would also affect the same terms in the other patents.

Thus, a finding of inequitable conduct during the prosecution of the '882 patent should render all three patents-in-suit unenforceable.

V. CONCLUSION

For all of the foregoing reasons, Smith & Nephew respectfully requests that the patents in suit be declared unenforceable due to inequitable conduct.

Dated: June 9, 2003

FISH & RICHARDSON P.C.

By: _____

William J. Marsden, Jr. (#2247)
Keith A. Walter, Jr. (#4157)
919 N. Market Street, Suite 1100
Wilmington, DE 19899-1114
Telephone: (302) 652-5070

Kurtis D. MacFerrin
500 Arguello Street, Suite 500
Redwood City, CA 94063
Telephone: (650) 839-5070

Mark J. Hebert
Thomas M. Johnston
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070

Attorneys for Defendant
SMITH & NEPHEW, INC.

CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of June, 2003, a true and correct copy of SMITH & NEPHEW'S OPENING BRIEF IN SUPPORT OF ITS INEQUITABLE CONDUCT CASE was caused to be served on the attorneys of record at the following addresses as indicated:

BY HAND DELIVERY
Jack B. Blumenfeld, Esq.
Morris, Nichols, Arsht & Tunnell
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347

Attorneys for Plaintiff
Arthrocare Corporation

BY FEDERAL EXPRESS
Matthew D. Powers
Jared Bobrow
Perry Clark
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065 -1175

Attorneys for Plaintiff
ArthroCare Corporation

BY HAND DELIVERY
Steven J. Balick, Esquire
Ashby & Geddes
222 Delaware Avenue
Wilmington, DE 19801

Attorneys for Counterclaim Defendants,
Ethicon, Inc.

William J. Marsden, Jr.

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